

**REMARKS**

Applicant has amended the specification for clarification, grammatical corrections, and consistency. No new matter has been added to the specification.

The drawings and claims 1, 4, 9, 11, 14 and 15 have objected to due to the terminology "housing" and "barrier" in the claims which are not shown in the drawings. Applicant has amended the claims to delete these terms, such that the objection is moot.

Claims 1-10 have been rejected under 35 U.S.C. § 102 as being anticipated by Babb. Claims 11-16 have been rejected under § 103 as being obvious over Babb in combination with Six. Claims 17 and 18 have been rejected as being obvious over the combination of Babb and Six. Claim 18 has been rejected under § 103 as being obvious over Babb, Six and Linder. Claim 20 has been rejected under § 103 as being obvious over Babb, Six and Kaigler. Applicant respectfully traverses these rejections, and requests reconsideration of the claims.

Claims 1-20 have been provisionally rejected for obviousness type double patenting based on Applicant's co-pending applications Serial No. 10/981,036. Since the present application is the parent of the '036 application, Applicant will file a terminal disclaimer in the '036 application if necessary to overcome an obviousness-double patenting rejection which is not a provisional rejection.

**A. Independent Claim 1 Distinguishes Over Babb**

Claim 1 has been amended to provide that the carbon dioxide indicator is mounted on an exterior portion of the second tube of the adaptor. As seen in Figure 1, and as described in the specification at page 5, line 17-22, the carbon dioxide indicator 36 is housed within a casing ring 32 which is placed over the second tube 28 of the adaptor 12. This limitation is not met by Babb.

Babb discloses a carbon dioxide indicator 56 which is mounted inside the adaptor 34, contrary to exterior mounting requirement of claim 1.

There is no teaching or suggestion in any of the cited secondary references to change the interior location of the Babb carbon dioxide indicator to an exterior position.

Thus, claim 1 distinguishes over the cited references so as to be in proper form for allowance. Claims 2-4 and 7-10 depend from claim 1 and should be allowable as dependent from an allowable base claim.

Claim 7 requires that the carbon dioxide indicator surrounds the second tube over in orifice in the tube. Since the Babb carbon dioxide indicator is within the tube, as opposed to surrounding the tube, claim 7 further distinguishes over the cited reference as to be in proper form for allowance.

Claim 8 requires that the carbon dioxide indicator is paper. Babb does not disclose a paper CO<sub>2</sub> indicator. Rather, Babb discloses the use of a liquid within the cavity 62, as described as column 14, lines 26-31. Therefore, Babb does not anticipate claim 8.

**B. Independent Claim 11 is Not Obvious Over Babb and Six**

Claim 11 is directed towards a combination including an endotracheal tube, an adaptor attached to the endotracheal tube, a stylet placed within the endotracheal tube, and a carbon dioxide indicator. Claim 11 further provides that the endotracheal tube, adaptor, stylet and carbon dioxide indicator are "pre-assembled and packaged as an assembly." As described in the specification, by packaging the components in a pre-assembled state, critical time is saved when the medical personnel must use the assembly on a patient. See page 2, lines 25-31; and page 6, line 10 – page 8, line 11. While Babb and Six may be combined to yield an endotracheal tube with a stylet extending therethrough, there is nothing in these references to teach or suggest that

the endotracheal tube, stylet, adaptor and carbon dioxide indicator all be pre-assembled and be packaged as an assembly, in accordance with claim 11. Therefore, the Examiner has failed to set forth a *prima facie* case of obviousness, such that the obviousness rejection should be withdrawn. Claim 11 distinguishes over the cited references, alone or combination, so as to be in proper form for allowance, along with claims 12, 13 and 15 depending there from.

As the Federal Circuit has explained, "Under § 103, teachings of references can be combined only if there is some suggestion or incentive to do so. . . . The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." (*emphasis added*). In re Fritch, 23 U.S.P.Q. 1780, 1783-84 (Fed Cir. 1992). More particularly, the Federal Circuit has stated that for a § 103 obviousness rejection based upon a combination of patents, there must be "some objective teaching" leading to the combination. In re Fritch, 972 F.2d 1260, 1265 (Fed. Cir. 1992). As further explained by the Federal Circuit at In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999), this showing must be "clear and particular."

Also, as further stated by the Federal Circuit, "an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would compel one skilled in the art do what the patent applicant has done." Ex parte Levengood, 28 U.S.P.Q.2d 1300, 1302 (Fed. Cir. 1993).

As the Board of Patent Appeals and Interferences has stated, citing references which merely indicate that isolated elements and/or features recited in claims are known is not sufficient basis for concluding that the combination of claimed elements would have been obvious." Ex parte Hiyamizu, 10 U.S.P.Q.2d 1393, 1394 (B.P.A.I. 1988).

In short, as stated by the Federal Circuit,

"It is wrong to use the patent-in-suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims-in-suit." Orthopedic Equipment Company v. United States, 702 F.2d 1005, 1012, 217 U.S.P.Q. 193, 199 (Fed. Cir. 1983).

Here, there is no clear and objective teaching in Babb or Six that the components of Babb and Six be pre-assembles and packaged, in accordance with the limitations of claim 11.

Therefore, the § 103 rejection of claim 11 should be withdrawn. Claim 11 is allowable, along with claims 12, 13 and 15 depending therefrom.

#### **C. Claim 17 is Not Obvious in View of Babb and Six**

Independent claim 17 is directed towards a method of placing an endotracheal tube into a patient, with the first step being "providing a pre-assembled and packaged endotracheal tube, adaptor attached to the endotracheal, carbon dioxide indicator, and stylet extending through the endotracheal tube and the adaptor." As discussed above with respect to claim 11, there is no teaching or suggestion in Babb or Six for a method wherein a pre-assembled and packaged endotracheal tube, adaptor, carbon dioxide indicator, and stylet are provided for use in a patient intubation. As described in the specification this method saves valuable and critical time for the medical personnel who are attending the patient. Thus claim 17 distinguishes over the cited references so as to be in proper form for allowance, along with dependent claim 19 and 20.

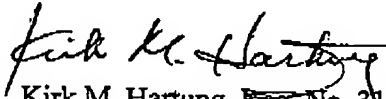
#### **D. Conclusion**

In view of the foregoing, each of the independent claims 1, 11 and 17 distinguish over the cited references as to be allowable, along with the claims depending therefrom. Thus, the § 102 and § 103 rejections should be withdrawn and a notice of allowance issued.

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



Kirk M. Hartung, Reg. No. 31, 021  
McKEE, VOORHEES & SEASE, P.L.C.  
801 Grand Avenue, Suite 3200  
Des Moines, Iowa 50309-2721  
Phone No: (515) 288-3667  
Fax No: (515) 288-1338  
**CUSTOMER NO: 22885**

Attorneys of Record

- flcu -